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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,764	07/27/2001	Tiziana Bisogno	2865-332	7567

23117 7590 12/02/2003
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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
1623	12

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,764

Applicant(s)

BISOGNO ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-26 and 51-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 22-26 and 51-53 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

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DETAILED ACTION

The Amendment A (paper 11) filed September 16, 2003 has been received, entered into the record and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-21 have been cancelled.
2. Claims 22-26 have been amended.
3. New claims 51-53 have been added.
4. Remarks/Arguments drawn to rejections.

Claims 22-26 and 51-53 are pending.

The Counsel's understanding that claims 27-50 have been withdrawn from consideration is correct.

Claim Rejections - 35 USC § 102

The objections to Claims 24-25 as being dependent on rejected base claims made in the previous office action is being withdrawn and the following rejection is made of record.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Koda et al (EP 0613879), Morre et al (European Journal of Cancer, 1996, 32A(11), 1995-2003) and Janusz et al (Journal of Medicinal Chemistry, 1993, 36, 2595-2604).

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Koda et al disclose a compound of formula I (see page 3, line 19 through page 4, line 2), wherein A represents the group shown on lines 40-45 in which R_{21} and R_{22} individually representing hydroxy and lower alkoxy (methoxyl) groups, n_2 is 1 and R_{11} and R_{12} individually represent hydrogen, hydroxy or lower alkoxy (can be a methoxyl). Koda et al also disclose (page 59, lines 20-25) that these compounds are effective against asthma.

Morre et al teach the inhibition of melanoma cells by capsaicin (see abstract and discussion on page 2000).

Janusz et al teach the antiinflammatory and antinociceptive activity of vanilloids, especially the oleylamide, palmitoylamide and the arachidonoylamide (see abstract, Table III entries 25, 26, 38-46 on page 2599 and page 2601, right column, lines 13-28). At page 2599 of Janusz et al, Table III, entry numbers 38-41, the R group is derived from oleic acid, which is also one of the monoacyl radicals for the R group recited in instant claims 24 and 25.

These disclosures of Koda, Morre and Janusz are deemed to meet the limitations of claims 24 and 25.

Response to Remarks/Arguments

Applicant's arguments regarding the anticipation rejections of claims 22, 23 and 26 have been considered but are not found to be persuasive.

Applicants argue that none of Koda et al, Morre et al and Janusz et al describe or suggest a method of functionally stimulating the peripheral receptor CB1 of cannabinoids by administering a compound of formula (I) of the instant application.

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Koda et al disclose compounds encompassed by instant formula (I) for the treatment of asthma, which is also one of the pathologies in the embodiment of the instant invention. Koda et al also disclose the preparation of non-toxic salts of the compounds of formula (I). The acids used for making these salts include hydrochloric, citric, maleic and acetic acids (page 9, lines 8-10), which are also the acids recited in instant claim 51.

Janusz teaches the use of the compounds of his invention as anti-inflammatory agents and Morre et al teach the use of capsaicin for the inhibition of growth of tumor cells both of which are also pathologies in the embodiment of the instant invention.

Even though the prior art does not explicitly state a method of stimulating the peripheral receptor CB1 of cannabinoids it is inherent that the compounds of the instant invention and those of the prior art which are used for treating asthma, inhibition of cell proliferation (tumor) and anti-inflammatory action all function via the same mechanism.

Conclusion

1. Claims 22-26 and 51-53 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1200